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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,663	01/29/2004	Yossi Gross	SC&C-100US	5982

23122 7590 06/19/2007

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,663	GROSS ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/29/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-173* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-173* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-130 are drawn to apparatus for drug administration Comprising: an ingestible capsule, which comprises: a drug, stored by the capsule; an environmentally-sensitive mechanism, adapted to change a state thereof responsive to a disposition of the capsule within a gastrointestinal tract of a subject; and a driving mechanism which, in response to a change of state of the environmentally-sensitive mechanism, is adapted to drive the drug directly through an endothelial layer of the gastrointestinal tract classified in class 424 subclass 452.

II. Claims 131-136 are drawn to apparatus, comprising: a capsule adapted to travel through a gastrointestinal tract of a subject, the capsule comprising: first and second electrodes; and a control component, adapted to drive, at each of a plurality of sites longitudinally distributed along the gastrointestinal tract, an iontophoretic current that travels from the first electrode, through an endothelial layer of

the gastrointestinal tract, and to the second electrode classified in class 424 subclass 452 and 204/411.

III. Claims 137-142 are drawn to apparatus, comprising:
a capsule adapted to travel through a gastrointestinal tract of a subject, the capsule comprising: first and second electrodes; and a control component, adapted to drive, at each of a plurality of sites longitudinally distributed along the electrode, through an endothelial layer of the gastrointestinal tract, and to the second electrode classified in class 424 subclass 452, 204/411, 604/20 and 604/501.

IV. Claims 143-144 are drawn to apparatus, comprising:
a capsule adapted to travel through a gastrointestinal
tract of a subject, the capsule comprising: first and second electrodes; a coating on an outer surface of the capsule; and a control component, adapted to drive an iontophoretic current that travels from the first electrode, through an endothelial layer of the gastrointestinal tract, and to the second electrode, in response to a change of state of the coating. classified in class 424 subclass 452 and 604/501.

V. Claims145-149 are drawn to a method for administration of a drug, comprising: administering to a subject an ingestible capsule that includes a drug; detecting a disposition of the capsule within a gastrointestinal tract

of the subject; and in response to detecting the disposition, driving the drug directly through an endothelial layer of the gastrointestinal tract. classified in class 424 subclass 452.

VI. Claims 150-173 are drawn to an electrically assisted, drug-delivery system, comprising: a biologically inert and biologically compatible device, comprising: a power supply; a control component, in power communication with said power supply; and at least one apparatus for electrically assisted drug transport, said apparatus being in signal communication with said control component and in power communication with said power supply; and a drug attached to said device classified in class 424 subclass 452 and 604/20.

2. The inventions are distinct, each from the other for the following reasons: Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01).

3. Inventions I and II -IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation and its effect. The apparatus of group I does not require electrode, where as the apparatus of group II requires

electrodes and iontophoretic current flowing through the electrode. Group III requires does not state the requirement of iontophoretic current and group IV requires a coating, which is not, required by group I.

4. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the apparatus claimed in group I can be utilized in taking images itself.

5. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case the apparatus of group I does not require electrical assistance. The environmentally sensitive mechanism could be color coatings and hence the inventions are distinct.

6. Inventions II and III -IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions). In the instant case, the different inventions have different modes of operation and its effect. The apparatus of group II requires electrodes and

iontophoretic current flowing through the electrode whereas the apparatus of Group III does not state the requirement of iontophoretic current and group IV requires a coating, which is not, required by group I.

7. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the apparatus of group II can be used to check images for cell structure.

8. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case the apparatus of group II is directed to an apparatus and group VI is directed to drug delivery system . Both the inventions have different mode of operation and effect.

9. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different design and modes of operation. Group III does not

require coatings as claimed in group IV which makes the design of the two inventions distinct with varying effects.

10. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the mode of administration could be a patch comprising electrodes and drug.

11. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case). In the instant case the images of the disposition of the drug can be taken with photosensitive nuclear medicines.

12. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case In the instant case the mode of administration could be a patch comprising electrodes and drug.

13. Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case). In the instant case the images of the disposition of the drug can be taken with photosensitive nuclear medicines.

14. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

15. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

16. Because these inventions are independent or distinct for the reasons given

above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

18. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.IO3(a) of the other invention.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-61971 The examiner can normally be reached on Monday-Friday from 8:30 A.M to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Snigdha Maewall

Art unit 1615

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600